THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

LABORATOIRES BIOVE, FRANCE
PUBLIC GMP DESK ASSESSMENT REPORT

MARCH, 2025

Part 1: General information about the company

1.1 Manufacturer's details	
Name of Applicant	Laprovet, 7 Rue du Tertreau, Arched'Oé 2, France Email: info@laprove.com
1.2 Inspected site Details	
Name & physical address of inspected manufacturing site	Laboratoires Biove, 3 rue de Lorraine, 62510 Arques, France
Name of Unit/ block/ workshop number inspected	B2 – for manufacturing of injectables B3 – manufacturing of powders B8 – manufacturing of injectables B6- Oral liquids
1.3 Inspection details	
Date of desk review	26th July, 2024
Date of last inspection by the SRA, WHO-PQ or EAC / SADC for production line applied at TMDA	23rd to 26th October, 2023
1.4 Brief report of the activities undertaken at the site	
Summary of the activities performed at the site	Manufacturing, packaging and quality control testing of veterinary medicines in the form of; • General Formulations in form of SVP, LVP, OSD (powders, premixes) oral liquids and external preparations. • Penicillin in the form of LVP and SVP, OSD (powders, premixes) oral liquids and external preparations, and Hormones
Production lines applied at TMDA	• General formulations in form of oral liquids, OSD (powders) and small volume parenteral (solution for injection)

	• Penicillin in form of Small volume parenteral (lyophilized powder for injection)

Part 2: Review of submitted documentary evidence

2.1. Site master file

Site Master file number effective from 6th November 2023 was submitted. The SMF was prepared as per requirements stipulated in the TMDA (Good Manufacturing Practice Enforcement) Regulations, 2018.

2.2. List of all regulatory inspections carried out in the past three years.

The facility was inspected by National Veterinary Medicines Agency, France on 28th March, 2024 and ANSES ANMV, France on 23rd - 26th October, 2023

2.3. Manufacturing license and GMP permit granted by the local National Medicines Regulatory Authority (NMRA).

A valid manufacturing license issued by NRA i.e. the Anses ANMV (France) on 30th May, 2024 was provided.

2.4. Valid GMP certificate issued by stringent medicines regulatory authority and/or that from WHO prequalification and Regional Harmonization Initiatives (whichever is applicable) for inspection carried out within the past three years for production line(s) applied at TMDA.

2.4.1. Name of SRA/WHO-PQ/RECs

The SRA which inspected the facility was ANSES ANMV, France

2.4.2. Dates of inspection

23rd to 26th October, 2023

2.4.3. Scope of GMP certificates/ List of compliant production line

The inspected and compliant production lines were:

- General Formulations in form of SVP, LVP, OSD (powders, premixes) oral liquids and external preparations.
- Penicillin in form of LVP and SVP, OSD (powders, premixes) oral liquids and external preparations
- Hormones

2.4.4. A confirmation by the senior QA representative that a full SRA audit covering the product(s) has been performed and all matters dealt with and attest to the authenticity of the information

Not provided, but the site was confirmed to be GMP compliant in the Eudra GMP database for the production line under TMDA scope.

2.5. Regulatory Actions against the facility that were taken in the past three (3) years.

The applicant had submitted a declaration confirming that there were no market complaints received in the past three years and as per TMDA's Substandard and Falsified register, there were no product complaints and recall of products from this facility.

2.6. Market complaints in the last three years for products applied at TMDA

The applicant had submitted a declaration confirming that there were no market complaints received in the past three years and as per TMDA's Substandard and Falsified register, there were no product complaints and recall of products from this facility.

Part 3: Conclusion

Based on the desk assessment and evidence(s) provided **Laboratoires Biove, 3 rue de Lorraine, 62510 Arques, France** is considered to be operating at an acceptable level of compliance with the requirements of the Tanzania Food, Drugs and Cosmetics (Good Manufacturing Practice Enforcement) Regulations, 2018 for manufacturing of **General formulations in forms of oral liquids (solutions), OSD (powders) & Small Volume Parenteral (solution for injection) and Penicillin in form of Small Volume Parenterals (lyophilized powder for injection) for veterinary use**

This TPIR will remain valid for three (3) years provided that the facility will remain compliant following any inspections conducted in the period.

Part 4: References

1. TMDA (2023) Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities, First Edition, Dodoma, Tanzania

2. TMDA Good Manufacturing Practices Manual and SOPs, Tanzania Medicines and Medical Devices Authority, Dar-es-Salaam, Tanzania

3. Tanzania Medicines and Medical Devices Act, Cap 219.

4. TMDA, Good Manufacturing Practices Enforcement Regulations (2018), Tanzania Medicines and Medical Devices, Dar-es-Salaam, Tanzania